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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,972	03/30/2004	Chris Lee	9450-13DV	8626
20792	7590	08/01/2008	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			LUONG, PETER	
PO BOX 37428			ART UNIT	PAPER NUMBER
RALEIGH, NC 27627			3737	
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08/01/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/814,972	LEE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Peter Luong	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 5/13/2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) 45 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-44 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/13/2008 has been entered.

### ***Election/Restrictions***

2. Newly submitted claim 45 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claimed subject matter is directed to a connector and not a guidewire.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 45 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Objections***

3. Claims 2 and 16 are objected to because of the following informalities: in claim 2 "the lumen" lacks antecedent basis, in claim 16 it is unclear as to what further structural limitation is set forth. Appropriate correction is required.

4. Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 sets forth the identification parameter to be at least one of the following: an electrical circuit, a mechanical configuration, optical or visual indicia. It is unclear how the limitations of claim 24 further limit one of these parameters.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed fails to disclose wherein the guidewire, connector, or guidewire and connector combination comprises an identification parameter that is at least one of the following: an electrical circuit, a mechanical configuration, optical or visual indicia, whereby the identification parameter allows assembly only for a suitable connector and guidewire combination.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. In claims 1 and 25, the claims contain subject matter which is not directed to the claimed invention. In view of the recitation of “a proximal end sized and shaped **for insertion into a connector**”, the connector has not been positively set forth as being part of the claimed invention. Therefore, claimed subject matter directed to the connector is not part of the claimed invention and as such is not given patentable weight.

10. Claims 23, 27-32, 34-36, and 39-44 are directed to the connector and are not part of the claimed invention, therefore are not given patentable weight. The Examiner notes that any amendment to include the connector into the claimed invention would raise issues regarding election by original presentation.

#### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-4, 9-12, 16-23, and 25-44 are rejected under 35 U.S.C. 102(b) as being anticipated by McKinnon (US 5,792,055).

13. With respect to claims 1-4, 9-12, 16-23, and 25-44, the patent of McKinnon discloses a MRI guidewire (abstract) comprising an inner conductor (13, i.e. center

conductor), an outer conductor (15), a distal end sized and shaped for insertion into a subject to receive MRI signals (fig 1), a proximal end sized and shaped for insertion into a connector (col. 4, lines 54-65; see fig 1, it is inherent for a connection means to connect the guidewire to the control station), an insulated area between the outer and inner conductor (14), and the guidewire is connected to the MRI scanner and MRI circuits (fig. 1). With respect to the inner and outer conductor contacts, the Examiner interprets the surface of the inner and outer conductors to be the contacts as any conductive material touching the surface of the conductor would be electrically coupled to the conductor. McKinnon discloses the inner conductor extending beyond the outer conductor (col. 4, ln. 57-65). (col. 4, line 66 to col. 5, line 27; figs. 1-3). With respect to claim 16, the Examiner notes that any material can be made sterilizable. With respect to claim 22, McKinnon discloses an extension attachment at the proximal end of the guidewire (col. 5, ln. 7-9). With respect to claim 23 and 37, it is inherent for connectors and cables to have a specific mechanical configuration. With respect to claim 38, the Examiner notes that any device can be disposed of after a single-use. Claims 23, 27-32, 34-36, and 39-44 are directed to the connector and are not part of the claimed invention, therefore are not given patentable weight

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055).

17. McKinnon discloses the subject matter substantially as claimed except for wherein the identification parameter is a unique serial number.

18. However, it is well known in the art of cable and connectors for manufacturers to imprint serial numbers on their products (i.e. lot numbers) such that if a certain batch is defective the manufacturers are able to effectively recall the products.

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an identification parameter such that defective products can be identified.

20. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) in view of Glowinski et al. (US 5,868,674).

21. The patent of McKinnon discloses the subject matter substantially as claimed except for wherein the guidewire diameter is between about 0.012 inches and 0.038

inches and an inner conductor diameter to be between about 0.004 inches and about 0.012 inches.

22. However, Glowinski et al. teaches a MRI catheter with a diameter between 0.3 mm (0.0118 inches) to 3 mm (0.118 inches) for insertion into a patient (fig. 1).

23. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the guidewire diameter to be about 0.012 inches and 0.038 inches as a change in size is within the skill level of one of ordinary skill in the art. Furthermore, it would have been obvious for the inner conductor to be smaller than the guidewire.

24. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) in view of Lardo et al. (US 6,675,033).

25. The patent of McKinnon discloses the subject matter substantially as claimed except for wherein the guidewire comprises titanium or nitinol.

26. However, Lardo et al. teaches a MRI guidewire probe comprising known super-elastic material comprising titanium and nitinol (col. 9, lines 25-50).

27. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the super-elastic material as taught by Lardo et al. those materials are known for their high biocompatibility (col. 9, lines 32-35).

28. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) in view of Atalar et al. (US 6,628,980).

29. The patent of McKinnon discloses the subject matter substantially as claimed except for wherein the guidewire comprises titanium or nitinol.

30. However, Atalar et al. teaches a MRI guidewire probe comprising known super-elastic material comprising titanium and nitinol (col. 11, lines 56-63).

31. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the super-elastic material as taught by Atalar et al. those materials are well known MRI compatible materials (col. 11, lines 56-63).

***Response to Arguments***

Applicant's arguments with respect to claims 1-44 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Luong whose telephone number is (571)270-1609. The examiner can normally be reached on Monday - Friday, 9:30 a.m. - 6:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737

/P. L./  
Examiner, Art Unit 3737